



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2012-0589; FRL-9401-8]

#### Fomesafen; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of fomesafen in or on multiple commodities which are identified and discussed later in this document.

Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

#### SUPPLEMENTARY INFORMATION).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0589, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW, Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at

<http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0589 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0589, by one of the following methods:

- *Federal eRulemaking Portal: <http://www.regulations.gov>.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at

<http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of September 28, 2012 (77 FR 59578) (FRL-9364-6) and June 5, 2013 (78 FR 33785) (FRL-9386-2), EPA issued documents pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 2E8061 and 3E8167) by IR-4, IR-4 Project Headquarters, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petitions requested that 40 CFR 180.433 be amended by establishing tolerances for residues of the herbicide fomesafen, 5-[2-chloro-4-(trifluoromethyl)phenoxy]-N-(methylsulfonyl)-2-nitrobenzamide, in or on cantaloupe; cucumber; pea, succulent; pumpkin; squash, summer; squash, winter; and watermelon all at 0.025 parts per million (ppm); and soybean, vegetable, succulent at 0.05 ppm (2E8061); and bean, lima, succulent at 0.05 ppm (3E8167). The documents referenced a summary of each petition prepared by Syngenta Crop Protections, LLC, the registrant, which are available in the docket, <http://www.regulations.gov>. One public comment was received on the notice of filing for PP 3E8167. EPA's response to the comment is discussed in Unit IV.C.

Based upon review of data supporting the petition, EPA corrected the commodity name for certain crops for which a tolerance was proposed as explained in Unit IV.D.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fomesafen including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fomesafen follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of

the sensitivities of major identifiable subgroups of consumers, including infants and children.

In the subchronic and chronic fomesafen toxicity studies in rats and mice, food consumption, food efficiency, body weight, body weight gain, and histopathological changes in the liver were parameters that were most often affected. In addition, dogs and mice also showed hematological changes (e.g., decreased erythrocyte count, hemoglobin, or hematocrit).

In the developmental studies, post-implantation loss was noted but no quantitative or qualitative evidence of increased susceptibility to fomesafen was seen following *in utero* exposure to rat or rabbit fetuses in prenatal developmental studies or postnatally in rat 2-generation reproduction study.

Acute neurotoxicity studies indicate fomesafen may cause neurotoxicity (decreased motor activity) at the same dose level as systemic toxicity. Although suppression of anti-sheep red blood cell immunoglobulin (SRBC IgM) response was noted in the immunotoxicity study, the selected endpoints for risk assessment are protective of this effect.

Carcinogenicity was not observed in the rat chronic toxicity/carcinogenicity study. Although liver tumors were seen in the mouse carcinogenicity study, EPA classified fomesafen as “Not Likely to be Carcinogenic to Humans” because the mode of action for fomesafen-induced hepatocarcinogenesis in mice is unlikely to take place in humans. Fomesafen was not considered to be mutagenic.

Specific information on the studies received and the nature of the adverse effects caused by fomesafen, as well as the no observed adverse effect level (NOAEL) and the

lowest observed adverse effect level (LOAEL) from the toxicity studies, can be found at <http://www.regulations.gov> in document: “Fomesafen Sodium: Human Health Risk Assessment for the Section 3 Registration Action on Cantaloupe, Cucumber, Pea (Succulent), Pumpkin, Summer Squash, Winter Squash, Watermelon, Soybean (Succulent) and Lima Bean (Succulent),” dated July 18, 2013 at page 27 in docket ID number EPA-HQ-OPP-2012-0589.

*B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for fomesafen used for human risk assessment is shown in Table 1. of this unit.

**Table 1.--Summary of Toxicological Doses and Endpoints for Fomesafen for Use in Human Health Risk Assessment**

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children)	NOAEL = 100 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Acute RfD = 1 mg/kg/day  aPAD = 1 mg/kg/day	Acute neurotoxicity test in the rat. LOAEL = 250 mg/kg/day based on decreased body weight and motor activity (horizontal and vertical activity and time in central quadrant) in males.
Chronic dietary (All populations)	NOAEL = 0.25 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Chronic RfD = 0.0025 mg/kg/day  cPAD = 0.0025 mg/kg/day	Chronic toxicity/ carcinogenicity in the rat. LOAEL = 5 mg/kg/day based on hyalinization of the liver in males.

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest observed adverse effect level. NOAEL = no observed adverse effect level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor.  $UF_A$  = extrapolation from animal to human (interspecies).  $UF_H$  = potential variation in sensitivity among members of the human population (intraspecies).

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fomesafen, EPA considered exposure under the petitioned-for tolerances as well as all existing fomesafen tolerances in 40 CFR 180.433. EPA assessed dietary exposures from fomesafen in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.



Such effects were identified for fomesafen. In estimating acute dietary exposure, EPA used Dietary Exposure Evaluation Model - Food Consumption Intake Database (DEEM-FCID), ver. 3.16 which incorporates consumption data from the United States Department of Agriculture (USDA) 2003 – 2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEA). Acute analysis assumed 100 percent crop treated (PCT), DEEM 7.81 default concentration factors, tolerance-level residues for all existing and proposed crop uses.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used DEEM-FCID, ver. 3.16 which incorporates consumption data from USDA 2003 – 2008 NHANES/WWEA. As to residue levels in food, EPA analysis assumed 100 PCT and tolerance-level residues for all existing and proposed crop uses.

iii. *Cancer.* Based on the data summarized in Unit III.A., a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for fomesafen. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fomesafen in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fomesafen. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Screening model Tier II Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) was used to calculate surface water estimated drinking water concentrations (EDWCs). Groundwater EDWCs for fomesafen were calculated using Tier 1 Pesticide Root Zone Model Ground Water (PRZM GW). Acute exposures are estimated to be 34.8 parts per billion (ppb) for surface water and 51.8 ppb for ground water.

Chronic exposures for non-cancer assessments are estimated to be 13.1 ppb for surface water and 32.3 ppb for ground water.

Modeled estimates of drinking water concentrations are based on ground water EDWCs, which were highest among surface water and ground water EDWCs (representing worst case), were directly entered into the dietary exposure model.

For acute dietary risk assessment, the water concentration value of 51.8 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 32.3 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Fomesafen is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning

the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found fomesafen to share a common mechanism of toxicity with any other substances, and fomesafen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fomesafen does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

*D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The pre- and postnatal database for fomesafen includes a prenatal developmental toxicity study in rabbits, two prenatal developmental toxicity studies in rats, and a 2-generation reproduction toxicity study in rats. The rabbit developmental study was classified as unacceptable because of bacterial infection in the colony; however, the study provided information to assess potential

developmental toxicity in rabbits. There was no significant difference between the treated and control animals for developmental abnormalities in the rabbit study. In the two rat developmental studies (considered together), developmental effects (postimplantation loss) occurred at the same dose causing maternal toxicity (staining of the ventral fur and significantly decreased body weight gain ( $> 10\%$ )). In the rat reproduction study, offspring effects (increased incidence of liver hyalinization in males) occurred at the same dose causing parental effects (liver histopathology in males and females of both generations).

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for fomesafen is complete. The developmental toxicity study in rabbits, classified unacceptable due to mortality from bacterial infections, showed no evidence of increased susceptibility of rabbit fetuses due to the treatment with fomesafen. Therefore, the lack of an acceptable developmental toxicity study in non-rodents was not considered a data gap.

ii. There is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. In an acute neurotoxicity screening battery in rats, decreased motor activity (horizontal and vertical activity and time in central quadrant) was observed at the same dose that resulted in general systemic toxicity. In the subchronic neurotoxicity test, neither general systemic toxicity nor neurotoxicity was observed at the highest dose tested. All points of departure used in the risk assessment are protective of any potential neurotoxicity.

iii. There is no evidence that fomesafen results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. The 2-generation reproduction study in rats did not show evidence of increased susceptibility to fomesafen.

iv. There are no residual uncertainties identified in the exposure databases. Tolerance level residues and 100 PCT were assumed for all food commodities. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fomesafen in drinking water. These assessments will not underestimate the exposure and risks posed by fomesafen.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fomesafen will occupy < 1 % of the aPAD for all population subgroups, including all infants (< 1 year old), the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fomesafen from food and water

will utilize 77% of the cPAD for all infants (< 1 year old) the population group receiving the greatest exposure. There are no residential uses for fomesafen.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- or intermediate-term residential exposure plus chronic exposure from food and water (considered to be a background exposure level). Short- and intermediate-term adverse effects were identified; however, fomesafen is not registered for any use patterns that would result in short- and intermediate-term residential exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for fomesafen.

4. *Aggregate cancer risk for U.S. population.* Based on the data summarized in Unit III.A., fomesafen is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to fomesafen residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (high performance liquid chromatography method with tandem mass spectrometry detection (LC/MS/MS) method (GRM045.01A)

is available to enforce the tolerance expression. The validated limit of quantitation (LOQ) of the method is 0.02 ppm.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

#### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Codex has not established maximum residue limits (MRLs) for residues of fomesafen.

#### *C. Response to Comments*

The Agency received an anonymous public comment objecting to the proposed fomesafen tolerance on lima bean because of the amounts of pesticides already consumed and carried by the American population.

The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned completely. However, under the existing legal framework provided by section 408 of the FFDCA, EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute.

#### *D. Revisions to Petitioned-For Tolerances*

Petitioned-for tolerance levels in or on commodities were unchanged, however, the commodity name of certain proposed crops was changed to comply with current EPA commodity definitions, as follows: Winter, squash changed to squash, winter; vegetable, soybean, succulent to soybean, vegetable, succulent; and lima, bean to bean, lima, succulent.

### **V. Conclusion**

Therefore, tolerances are established for residues of the herbicide fomesafen, including its metabolites and degradates, in or on cantaloupe; cucumber; pea, succulent; pumpkin; squash, summer; squash, winter; and watermelon all at 0.025 ppm; soybean, vegetable, succulent at 0.05 ppm; and bean, lima, succulent at 0.05 ppm.

### **VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not



subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In

addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 17, 2013.

Lois Rossi,

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.433, add alphabetically the following commodities to the table in paragraph (a) to read as follows:

**§ 180.433 Fomesafen; tolerance for residues.**

(a) *General.* \* \* \*

Commodity	Parts per million
* * *	* *
Bean, lima, succulent	0.05
* * *	* *
Cantaloupe	0.025
* * *	* *
Cucumber	0.025
Pea, succulent	0.025
* * *	* *
Pumpkin	0.025
* * *	* *
Soybean, vegetable, succulent	0.05
Squash, summer	0.025
Squash, winter	0.025
* * *	* *
Watermelon	0.025

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